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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,404	03/04/2002	John N. Feder	8907-098-999	9646

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,404	FEDER ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004 and 13 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-9 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7-9* is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/094,964, which is a continuation-in-part of U.S. Application Serial Number 08/876,010.

Claims 1-6 and 10 have been canceled.

Claims 7-9 and 11 are currently pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 13, 2004 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over either U.S. Patent No. 6,025,130 to Thomas et al (A on form PTO-892) or U.S. Patent No. 6,140,305 to Thomas et al (B on form PTO-892).

It was previously stated: "The '130 and '305 patents each disclose wild type and mutant forms of the HH protein, which is the same protein disclosed instantly as HFE. For the purpose of the present discussion, the elements will be addressed as they appear in the '305 patent. Applicant is reminded that the term "having" is interpreted as an open term consistent with the recitation of "comprising" and the recitation of "having" in these claims therefore opens the claims up to include unrecited elements including the additional amino acid residues of the full-length protein. The '305 patent teaches the HH

gene product of SEQ ID NO: 2 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 1 as amino acid residues 1-276 [instant claim 7]. The '305 patent also teaches the mutant HH gene product of SEQ ID NO: 6 as a 348 amino acid residue polypeptide having instant SEQ ID NO: 2 as amino acid residues 23-298 [instant claim 8].

The '305 patent further teaches that the HH gene product possesses significant homology to HLA Class I molecules which are known to interact with β_2 microglobulin and that β_2 microglobulin knock-out mice developed symptoms of iron overload disease (column 14, lines 28-54 in particular) which is a phenocopy of human hemochromatosis (column 24, lines 4-13 in particular). The '305 patent further teaches that a mutation in the β_2 microglobulin binding domain of the HH gene product predicted to ablate binding of the gene product to β_2 microglobulin was common to the majority of patients with human hemochromatosis (column 14, lines 28-54 in particular). The ' 305 patent teaches that when this binding is lost, the protein no longer is located on the cell-surface (column 24, lines 4-13 in particular).

The '305 patent also teaches that the HH gene product can be purified by conventional affinity chromatography techniques based on its homology with MHC Class I molecules. The '305 patent teaches immobilization of β_2 microglobulin on an inert matrix for purification of the HH gene product (column 24, lines 15-48 in particular). Accordingly, the purification procedure results in the production of a composition comprising an HH gene product, or HFE polypeptide, having SEQ ID NO: 1 or 2 and a full length, wild type human β_2 microglobulin.

The prior art teachings do not specifically teach such a composition in a form "suitable for administration to a subject. However, it would have been well within the purview of one of ordinary skill in the art to subject the composition obtained from the aforementioned purification procedure to an exchange of buffer, for example, by dialysis. It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to exchange the purification buffer with one suitable for administration to a subject in order to administer the composition to β_2 microglobulin knock-out mice. One would have been motivated, with a reasonable expectation of success, to perform this buffer exchange and administer the composition to a knock-out mouse by the teachings of the '305 patent that the HH gene product possesses significant homology to HLA Class I molecules, that β_2 microglobulin knock-out mice developed symptoms of iron overload disease and that a mutation in the β_2 microglobulin binding domain of the HH gene product predicted to ablate binding of the gene product to β_2 microglobulin was common to the majority of patients with human hemochromatosis."

Applicant's arguments filed October 13, 2004 have been fully considered but they are not persuasive.

Applicant argues that the 103 rejection is not proper because the Examiner has failed to provide motivation. Applicant asserts that putting a composition of a polypeptide comprising SEQ ID NO: 2 and beta2 microglobulin (B2M) into knockout mice is counter intuitive because the mice are already iron overloaded. Applicant asserts that the introduction of the composition would only make the condition worse. However, the '305 patent teaches that human hemochromatosis (an iron overload condition) patients commonly have a mutation in the HH gene product that prevents HH association with B2M, causing HH protein to no longer be found on the cell surface. B2M knockout mice are iron overloaded and also do not have HH on the cell surface because there is no B2M present to bind HH to the cell surface. Restoring purified B2M and HH compositions to the mice would provide the presence of HH on

the cell surface, thereby alleviating the iron overload codition of the mice. Accordingly, the motivation for providing a composition "suitable for administration to a subject" was proper.

Conclusion

2. Claims 7-9 are allowed.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
March 21, 2005

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644